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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,738	06/19/2000	H. William Bosch	029318/0615	3886

7590 05/23/2003
Foley & Lardner
Washington Harbor
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/23/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/597,738

Applicant(s)

BOSCH ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-119 is/are pending in the application.
- 4a) Of the above claim(s) 65-78, 82, 83 and 102-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-64, 79-81, 84-101, 118 and 119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 65-78, 82, 83 and 102-117 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The rejection of claims 51-64, 79-81 and 118 under 35 U.S.C. 103(a) as being unpatentable over Wood et al (6,264,922 B1) is maintained.

The rejection of claims 51-64, 79-81 and 118 under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) is maintained.

The rejection of claims 84-101 and 118-119 under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al in view of Dalby et al (5,202,110) is maintained.

Double Patenting

The provisional rejection of claims 51-64, 79-81, 84-101 and 118-119 under judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/190,138, is maintained. This rejection was not addressed in the remarks filed on 03/03/03.

Response to Arguments

Applicant's arguments filed 03/03/03 have been fully considered but they are not persuasive. Applicant stresses that "the claimed invention is an improvement over the prior art, as prior to the present invention it was not known if liquid aerosols of nanoparticulate active agents could be designed in which each droplet contains at least one nanoparticulate active agent particle". This not commensurate with the scope of the

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claims because the claims are drawn to compositions and method of delivery of the compositions. Prior art of record, namely Wood et al and Wiedmenn et al disclose all the required components and elements of the said compositions and method of their delivery. In such cases, when the prior art meets the component limitations of the compositions, it is considered that the properties of the composition are inherent and will exist, even if they are not specifically mentioned by prior art. It is also noted that the droplets form after the composition is sprayed out of the aerosol, and their property and form could very well be a function of the aerosol device or other factors and not the composition itself.

Although applicant's remarks regarding the need for improving the dosing efficiency of aerosol preparations is understood and accepted, however there is no proof that the compositions disclosed by the prior art do not contain such property. In fact, Woods et al claims an aerosol of a dispersion of liquid droplets, wherein,.. the liquid **droplets** consist essentially of a liquid, a crystalline therapeutic agent... The term "droplets" is clearly implying that all droplets consist of a therapeutic agent.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
May 19, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER